cefar® basic

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OPERATING INSTRUCTIONS – ENGLISH

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1. INTRODUCTION

CEFAR Medical AB has been a medical supplier of professional TENS Pain Relief products for more than 30 years. The company was established in Sweden in 1975 and is currently represented in large parts of the world.

The Cefar stimulators are widely used and endorsed by medical professionals and top athletes around the world.

TENS is effective, has no side effects and it's economical. Through clinical research, areas of application for TENS and EMS are rapidly expanding. Cefar is working actively to further develop the method towards a natural treatment alternative for the consumer.

More information about TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscle Stimulation) and our products can be found on our web site: www.cefar.se

CEFAR BASIC is a dual channel (four electrodes) nerve stimulator (TENS) with non-independent channels. CEFAR BASIC is designed for use by both professionals and home users. Its three preset pain programs provides relief of a wide range of pains, like back pain and neck pain. The stimulator has buttons for setting of program, amplitude and timer. An automatic key lock is activated 10 seconds after the amplitude has been set.

2. MEDICAL BACKGROUND

WHAT IS TENS?

TENS = Transcutaneous Electrical Nerve Stimulation. TENS is an effective method offering Pain Relief. TENS utilises the nervous system's own pain relief mechanisms to ease both acute and chronic pain.

WHEN IS TENS USED?

Good results are observed in acute and long-term pain conditions of many kinds, but above all when the pain originates in joints, the skeleton, muscles, skin, viscera, or nervous system. In some cases, TENS on its own may be sufficient, and in other cases it may provide a valuable complement to other forms of treatment.

HOW DOES IT WORK?

With the Pain Relief programs, impulses are sent through the nerves to block the pain impulses. Pain Relief is usually most efficient during stimulation, but the effect can also last after the program has finished. It also increases the circulation. The Pain Relief programs do not always treat the cause of pain. If the pain persists, seek medical advice.

WHEN AND HOW SHOULD I USE TENS?

The programs in the CEFAR BASIC can be used on any occasion when Pain Relief or Muscle Relaxation is needed. All the programs can be used as often as required. Guidelines for using the treatment programs with indication examples, suggested electrode placements and recommended treatment time are included in this manual.

3. PRECAUTIONARY MEASURES

- Inspect the equipment prior to use.
- Use the stimulator only as stated in the operating instructions.
- Only Cefar accessories should be used with the stimulator

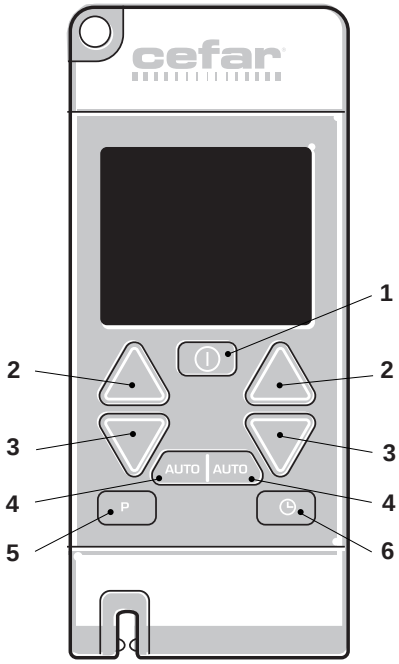
WARNING!

- People with implanted electronic equipment, such as pacemakers and intracardiac defibrillators, must not be treated with TENS.
- Pregnant women should not be treated with TENS during the first trimester (12 weeks).
- Due to the location of the carotid arteries and the carotid bodies, do not stimulate the front or sides of the neck, since a drop in blood pressure can occur.
- Stimulation should not take place while the user is connected to high-frequency surgical equipment. It may cause burn injuries on the skin under the electrodes, as well as problems with the stimulator.
- Do not use the stimulator in the vicinity of shortwave or microwave therapy equipment, since this may affect the output power of the stimulator.
- Keep the stimulator out of reach of children.

CAUTION

- Stimulate with precaution while treating angina pectoris.
- The electrodes are only to be placed on healthy skin. Avoid skin irritation by ensuring that good contact is achieved between electrodes and skin.
- Do not place electrodes directly over the uterus or connect pairs of electrodes across the abdomen if you are pregnant. The reason is that, theoretically, the current could affect the foetus's heart (although there are no reports of it being harmful).
- If skin irritation should occur, treatment should be temporarily discontinued. If problems continue, contact your health care provider. Hypersensitivity to tape and gel can occur in isolated cases. The problem usually disappears when the tape or gel is changed to another type.
- Do not use electrodes with a surface < 5 cm^2, as there will be a risk of suffering a burn injury. All Cefar electrodes fulfil this requirement. Caution should always be exercised with current densities > 2 mA/cm^2.
- Observe caution when using electrotherapy at the same time as the patient is connected to monitoring equipment with body worn electrodes. The stimulation might interfere with the signals to the monitoring equipment.
- Never open the battery cover during stimulation in order to avoid electrical shock.
- Turn off the stimulation before removing the electrodes from the skin. If an electrode comes off, turn off the stimulation before picking it up. Getting electrical stimulation through the fingers is unpleasant but not harmful.
- Observe caution when stimulating in the immediate vicinity of cellular phones that are switched on, since this may affect the output power of the stimulator.
- Observe caution if you use the stimulator while driving, unintentional stimulation changes might extract focus from the driving and create a hazardous situation.

4. OVERVIEW/CONTROL BUTTONS



1. ON/OFF

- Turns the stimulator on and off.
- Turns the stimulator off even when the key lock is activated.
- Can be used for terminating the stimulation at all times.

2. INCREASE (left and right channel)

- Increases the amplitude (intensity of stimulation). Press and hold the button to increase the amplitude continuously.
  Note! Always increase the amplitude cautiously.
- Terminates AUTO stimulation mode.
- Increases the number of minutes when setting the timer (right button).
- Used when turning the program lock on and off (left button). (PROFESSIONAL USE)

3. DECREASE (left and right channel)

- Decreases the amplitude (intensity of stimulation). Press and hold the button to decrease the amplitude continuously.
- Deactivates the key lock.
- Terminates AUTO stimulation mode.
- Decreases the number of minutes when setting the timer (right button).
- Used when turning the program lock on and off (left button). (PROFESSIONAL USE)

4. AUTO (left and right channel)

- Starts the AUTO test mode.
- Confirms the selected amplitude level in AUTO test mode.

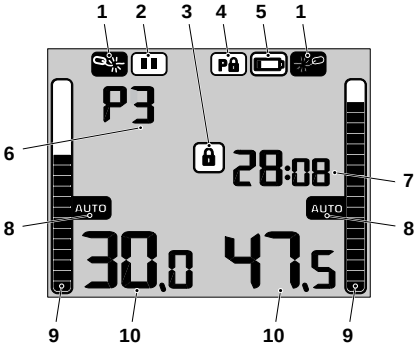
5. PROGRAM

- Selects programs 1-3.
- Pauses an ongoing program.
- Used when activating/deactivating the program lock.

6. TIMER

- Initiates the timer setting.

4. OVERVIEW/DISPLAY SYMBOLS



1. BROKEN CIRCUIT

Broken circuit. The reason for a broken circuit may be too high resistance or cable breakage. See chapter TROUBLESHOOTING.

2. PAUSE

Paused program.

3. KEY LOCK

Activated key lock. The key lock is automatically activated if no key is pressed for 10 seconds. Deactivate the key lock by pressing the left or right **DECREASE** button.

4. PROGRAM LOCK

Activated program lock.

5. BATTERY STATUS

Empty batteries. This symbol is shown when the batteries are almost empty.

6. PROGRAM NUMBER

Selected program number.

7. REMAINING TIME

Remaining program time in minutes and seconds. Time is flashing during timer setting.

8. AUTO STIMULATION MODE (left and right channel)

Activated automatic amplitude setting. “AUTO” is flashing during test mode and steady during stimulation.

9. AMPLITUDE BARGRAPH (left and right channel)

Selected amplitude as a bargraph.

10. AMPLITUDE LEVEL (left and right channel)

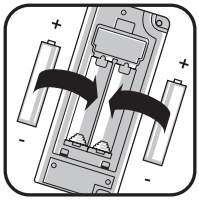
Selected amplitude in mA (not shown in Auto stimulation mode).

5. OPERATION

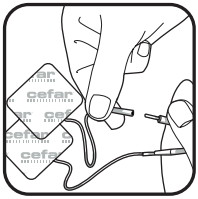
STEP-BY-STEP USE

1. INSERT THE BATTERIES

Insert the batteries (see chapter REPLACEMENT OF BATTERIES).

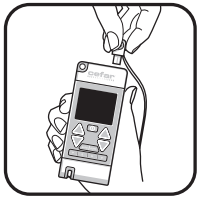


2. ATTACH THE ELECTRODES



A. Connect the electrodes to the cable.

B. Attach the electrodes to your body.



C. Connect the cable to the CEFAR BASIC.

3. SWITCH THE STIMULATOR ON

Press the **ON/OFF** button, ⏻ . This button can be used for terminating the stimulation at all times, even when the key lock is activated.

Always switch the stimulation off before removing electrodes from the skin.

4. SELECT A PROGRAM (1-3)

Press the **PROGRAM** button P repeatedly until the program of your choice is shown on the display.

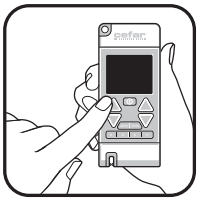
Note! When selecting programs the amplitude must be set to 00.0 mA for both channels.

For further information on the programs, see section PROGRAM GUIDE.

5. START THE STIMULATION

Press the **INCREASE** button △ for each channel until you reach a comfortable level of stimulation. Press and hold the button to increase the amplitude continuously.

Note! Always increase the amplitude cautiously!



The treatment time is preset, but can be changed by using the timer function, see section TIMER.

An automatically activated key lock prevents unintentional changes during treatment. The key lock is activated if no button is pressed for 10 seconds. Press any of the **DECREASE** buttons ▽ to deactivate the key lock.

When the program is finished, Remaining time “00:00” is flashing on the display.

The last used program is saved when the stimulator is turned off and then pre-selected the next time the stimulator is turned on.

The stimulator turns off after 5 minutes of inactivity to spare batteries.

AUTO STIMULATION MODE

To provide a pain relieving effect, the level of stimulation should be perceived as a little bit stronger than the pain intensity. Since the body initially adapts to the set level of stimulation, it is often required to adjust the amplitude a couple of times to reach the optimal level of stimulation.

By using the Auto stimulation mode the amplitude is automatically adjusted, and the optimal level is reached after a few minutes of stimulation.

To use the Auto stimulation mode:

Follow steps 1-4 in the section STEP-BY-STEP USE.

5. START THE AUTO TEST

Press the **AUTO** button

for the left or right channel. “AUTO” starts flashing on the display, and the amplitude increases gradually.

6. FINISH THE AUTO TEST

Press the **AUTO** button

again when you feel the stimulation at a *comfortable* level.

If you press **AUTO** too late, or want to start again for any reason, press the **AUTO** button again to start over.

7. REPEAT THE AUTO TEST FOR THE OTHER CHANNEL WITHIN 3 SECONDS

If you want to use the Auto stimulation mode for both channels, repeat steps 5-6 for the other channel.

8. THE STIMULATION STARTS

The program starts after a few seconds, and the amplitude is automatically adjusted to an optimal level of stimulation.

Even if you use Auto stimulation mode, you can increase or decrease the amplitude at any time by pressing the **INCREASE** or **DECREASE** buttons until the stimulation feels pleasant. If doing so, the automatic amplitude setting is lost.

TIMER

The preset treatment time is set to 30 minutes, but the timer function allows you to set the treatment time yourself. You have the option to change the timing from “- -“ to 60 minutes. If you choose to stay on “- -“, the stimulation will go on until you stop the stimulation manually.

To set the timer:

1. Select a program and start the stimulation, see section STEP-BY-STEP USE.
2. Press the **TIMER** button to initiate the timer function.

3. Increase the time by pressing the right **INCREASE** button . The time is increased by 1 minute each time you press the button. Decrease the time by pressing the right **DECREASE** button . The time is decreased by 1 minute each time you press the button. The time is flashing on the display, while setting the timer.
4. Press the **TIMER** button to confirm the timer setting.

PROGRAM PAUSE

You can pause the programs up to 5 minutes.

To pause a program:

1. If key lock is on, press any of the **DECREASE** buttons to deactivate it.
2. Press the **PROGRAM** button to pause the program.

Start stimulation again by pressing the **PROGRAM** button .

If stimulation is paused for more than five minutes, the stimulator turns off automatically to spare batteries.

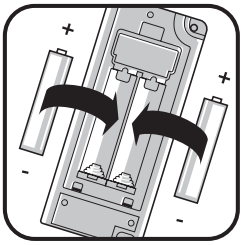
6. REPLACEMENT OF BATTERIES

A battery symbol is shown on the display when the batteries are almost empty . As long as the stimulator is working normally you can continue the treatment. When stimulation feels weaker than usual or the stimulator turns off, it is time to replace the batteries.

If the stimulator is not used for some time (approximately 3 months), the batteries should be removed from the stimulator.

The stimulator operates on either two non-rechargeable 1.5 V AA batteries or two rechargeable 1.2 V AA batteries, recharged in a separate charger.

The endurance of the batteries depends on the amplitude and number of channels activated during a program being used. For example, if you use one channel at P1 with an amplitude of 30 mA the non-rechargeable batteries last approximately 11 hours and rechargeable 7 hours.



REPLACING THE BATTERIES

1. Turn off the stimulator.
2. Locate the battery compartment on the back of the stimulator.
3. Remove the battery cover by sliding it downwards about 1 cm and then lifting it upwards.
4. Remove the batteries.
5. Insert the new batteries correctly according to the polarity markings (+ and –) inside the battery compartment, see picture.
6. Replace the battery cover.
7. Dispose of the exhausted batteries in accordance with local and national regulations.

NOTE! Non-rechargeable batteries may not be charged due to the risk of explosion.

7. PROGRAM GUIDE

Each program is described with the indications it is best suited to treat, how the electrodes should be placed, and how long the treatment should last. To each example of indication is at least one Electrode Placement number, which refers to the suggested electrode placements shown in the cover of the manual.

No.	Program name	Frequency	Pulse duration	Treatment time	Preset time
1	**Conventional TENS**	**80 Hz**	**180 µs**	No limit (minimum 30 minutes).	30 minutes
2	**Burst TENS**	**2 Hz**	**180 µs**	20–45 minutes, 3 times a day. Remember that Burst TENS can cause muscle soreness.	30 minutes
3	**Modulated pulse duration stimulation**	**80 Hz**	**70–180 µs**	No limit (minimum 30 minutes).	30 minutes

Program description	Examples of indications/ Electrodeplacement no.
Conventional TENS (high-frequency stimulation) is the first choice for both acute and long-term pain, both neurogenic and nociceptive. Conventional TENS is based on the Gate Control theory, which states that electric stimulation of A-beta fibers inhibits impulse transfer in the pain pathways. As a rule, the electrodes should be placed on or near the painful area, or over an area segmentally related to the painful area. Adjust the amplitude so that the stimulation gives strong, but pleasant paraesthesia – tingling. When using high-frequency stimulation, it's important to ensure that the patient has normal sensory of touch in the area where the electrodes are placed.	Neck pain ..... 1 Shoulder pain ..... 2 Elbow pain ..... 6 Rheumatic pain ..... 7 Fractured rib ..... 12 Lumbago ..... 10,11 Menstrual pain ..... 13 Phantom limb pain ..... 14 Hip pain ..... 16 Osteoarthritic pain in the knee... 17,18 Wound healing 19
Burst TENS (low-frequency stimulation) is usually most effective for radiating (projected) pain in the arms and legs (rhizopathy), for conditions with reduced or changed sensory of touch, for deep muscular pain, or when the post-treatment effect of Conventional TENS is too short. Burst TENS treatment alleviates pain by stimulating muscles to release the body's own morphine-like substances, endorphins. Place the electrodes on a muscle in the painful area so that a visible contraction occurs, or on acupuncture points in the painful area. The stimulation should feel pleasant and give visible muscle contractions. Remember that the patient often feels the stimulation clearly before contractions become visible.	Mononeuropathy ..... 8 Central pain ..... 4, 5 Cervical rhizopathy ..... 3 Sciatica ..... 15 Knee pain 18
Modulated pulse duration stimulation is a type of high-frequency stimulation where the pulse duration varies continuously. This can cause an undulating sensation, which may be more pleasant than a constant pulse duration. Use program 3 for pain alleviation and a massage effect on muscles like the trapezius.	Trapezius pain ..... 9 Lumbago ..... 10, 11 For more examples, see Program 1.

PROGRAM LOCK

The stimulator can be locked to prevent changing of programs.

To activate/deactivate the program lock:

1. Select the program you want to lock/unlock, see section STEP-BY-STEP USE.
2. Press the **PROGRAM** button [P] and the left **DECREASE** button simultaneously for 2 seconds.
3. Press the left **INCREASE** or **DECREASE** button . "ON" is shown on the left side of the display when activating the program lock and "OFF" when deactivating it. (The button toggles between ON and OFF).
4. Press **PROGRAM** button [P] to finish the program lock setting.

COMPLIANCE

Compliance gives you the possibility to monitor the use of the stimulator:

1. Turn the stimulator ON.
2. Press the **TIMER** button [◷] and the right **DECREASE** button simultaneously for 2 seconds.
3. The left side of the display shows the usage time in hours and the right side in minutes. To reset the usage time, press the right **DECREASE** button for 2 seconds.
4. Wait for 5 seconds or press **TIMER** button [◷].
5. The left side of the display shows the total usage time in hours and the right side in weeks. The total usage time cannot be reset.
6. Wait for 5 seconds or press the **TIMER** button [◷] to exit compliance mode.

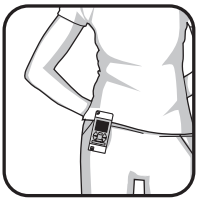
8. ACCESSORIES

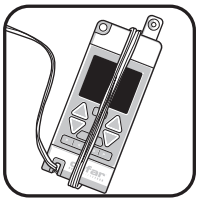
The electrodes will eventually wear out and need to be replaced. It is recommended to replace the electrodes after approximately 20-40 times of usage.

For purchase information, contact your Cefar dealer or visit www.cefar.se

CEFAR BASIC comes with a neck strap and a belt clip, allowing you to wear the stimulator around your neck or on your belt and have your hands free during treatment.

The cables are best preserved if left attached to the stimulator between sessions.





9. CARE INSTRUCTIONS

Taking care of and cleaning the Cefar equipment is simple with the following instructions:

- Keep stimulator and accessories in the original case when they are not in use. It may, however, be practical to allow the electrodes to remain on the body between treatments. Carbon rubber electrodes can generally remain for 2–3 hours without the electrode gel drying out (does not apply to adhesive gel). They must then be taken off, washed, and dried before being applied again. This is especially important for persons with sensitive skin. In connection with stimulation, make sure that the electrodes are firmly in place.
- When using carbon rubber electrodes, use plenty of electrode gel and avoid drying out by applying tape around all the edges of the electrodes. Rinse the carbon rubber electrodes and the skin with water after use. Do not use detergent for the electrodes.
- Self-adhesive multi-use electrodes are re-moistened if necessary with a few drops of water and kept air-tight (in a plastic bag) on protective paper when they are not in use.
- Never expose the stimulator to water. Wipe it off with a damp cloth if necessary.
- Do not jerk cables or connections.
- The cables are best preserved if left attached to the stimulator between sessions.

10. TROUBLESHOOTING

THE STIMULATION DOES NOT FEEL THE SAME AS USUAL

- Check that all settings are correct (see section STEP-BY-STEP-USE) and make sure that the electrodes are correctly placed.
- Slightly change the position of the electrodes.

THE STIMULATION FEELS UNPLEASANT

- The skin is irritated. For advice on skin care, see chapter PRECAUTIONARY MEASURE.
- The electrodes begin to lose their stickiness and do not stick properly to the skin. Moisten the adhesive surface with a few drops of water before placing on the skin.
- The electrodes are worn out and need to be replaced.
- There is insufficient electrode gel on the carbon rubber electrodes.
- Slightly change the position of the electrodes.

THE STIMULATION FEELS WEAK OR NOT AT ALL

- Check if the batteries need to be replaced, see chapter REPLACEMENT OF BATTERIES.
- Electrodes are too old and need replacement.

THE BROKEN CIRCUIT SYMBOL IS SHOWN ON THE DISPLAY SYMBOL

The broken circuit symbol indicates that the resistance is too high, or that a cable is broken.

- A too high resistance can be caused by a bad connection between the electrodes and your skin, or that the electrodes need to be replaced.
- A cable breakage can be checked by pressing the cable´s pins against one another while increasing the amplitude for the corresponding channel to 11 mA. If the amplitude now drops to 0.0 mA and starts flashing, the cable needs to be replaced.

Note! Never increase the amplitude above 20 mA when you check for cable breaks, since this can damage the stimulator.

THE STIMULATOR IS NOT WORKING

If the error symbol appears on the display when you start the stimulator, it means that the stimulator is broken and needs to be replaced.

Note! Do not use the stimulator – contact your Cefar dealer.

Cefar will only be responsible for service and repairs performed by Cefar or a distributor appointed by Cefar.

11. FREQUENTLY ASKED QUESTIONS (FAQ)

CAN ANYONE USE ELECTRICAL STIMULATION?

People with implanted electrical equipment for example a pacemaker and an intracardiac defibrillator must not be treated with electrical stimulation. Pregnant women should not use electrical stimulation during the first 12 weeks of the pregnancy. Read the safety precautions in this manual (PRECAUTIONARY MEASURES).

FOR HOW LONG TIME CAN I STIMULATE?

Follow the recommendations given by your health care provider. Generally high-frequency TENS (80 Hz) can be used without an upper time limit, but at least 30 minutes at each occasion. Low-frequency TENS (2 Hz) can cause sore muscles but normally 20-45 minutes 3 times a day is recommended.

CAN I USE TENS ON ALL KINDS OF PAIN?

TENS can be used for both acute and long time pain. General instructions can be read in chapter MEDICAL BACKGROUND. Contact your health care provider if the cause for and area of treatment is changed.

WHICH DISTANCE SHOULD I HAVE BETWEEN THE ELECTRODES?

It is recommended to have a distance of 3 to 30 cm between the electrodes.

FOR HOW LONG LAST THE ELECTRODES?

The self-adhesive electrodes last for approximately 20 to 40 occasions. The durability depends on how good the care and maintenance instructions are followed. Read the care and maintenance instructions delivered with the electrodes.

ARE THERE ANY SIDE EFFECTS WITH ELECTRICAL STIMULATION?

No, on the contrary to for example analgesic medicine, TENS stimulation is completely without side effects.

ARE THERE ANY PROOFS OF TENS WORKING AS AN ALLEVIATION OF PAIN?

TENS is an established and well-documented method that has been used by the medical service for many years. Research and medical studies are carried out all the time. Read more about current medical studies on Cefar´s home page www.cefar.se.

12. TECHNICAL DATA

CEFAR BASIC is a nerve stimulator (TENS) with two non-independent channels and three preset programs.

Treatment with electrical stimulation requires the stimulation current to penetrate the resistance of the skin and the electrode, about 1500 ohms. CEFAR BASIC can penetrate this resistance and maintain a current of up to 60 mA. With a change in load from 100 to 1500 ohms, the stimulation current changes less than 10% from the set value.

The stimulator operates on either two non-rechargeable 1.5 V AA batteries or two rechargeable 1.2 V AA batteries, recharged in a separate charger.

CEFAR BASIC

Number of channels	2 (non-independent)
Constant current	Up to a resistance of 1500 ohm
Stimulation current/channel	0–60 mA
Waveform	Asymmetrical biphasic pulse, 100% compensated
Number of preset programs	3
Stimulation forms	Conventional
	Burst
	Modulated pulse duration
Max pulse duration	180 µs
Max frequency	80 Hz
Timer	0 to 60 min
Environment for	
storage, use and shipping	Temperature 10°C–40°C
	Air humidity 30%–75%
	Air pressure 700 hPa–1060 hPa
Power source	2 x 1.5 V AA non-rechargeable or
	2 x 1.2 V AA rechargeable batteries
Current consumption for	
one channel, 80 Hz, 30 mA	150 mA
I r.m.s. max/channel	11 mA
Size	120 x 50 x 30 mm
Weight	ca. 180 g

KEY TO THE SYMBOLS

Read the operating instructions before to use.

Patient part type – Body Floating.

CE
0413

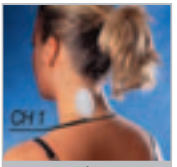
Complies with MDD 93/42/EEC requirements. Notified body Intertek ETL Semko (0413).

INFORMATION RELATED TO ELECTROMAGNETIC COMPATIBILITY (EMC).

CEFAR BASIC is designed to be used in typical domestic or clinical environments and approved according to the EMC safety standard of EN 60601-1-2.

CEFAR BASIC emits very low levels in the radio frequency (RF) interval. Therefore it is not likely to cause any interference in nearby electronic equipment (radios, computers, telephones etc.).

CEFAR BASIC is designed to withstand foreseeable disturbances originating from electrostatic discharges, mains supply magnetic fields and radio frequency transmitters (such as mobile telephones).



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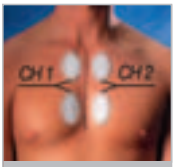

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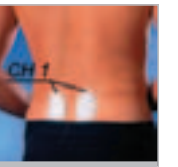

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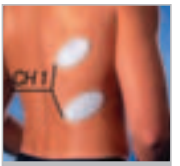

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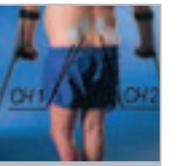

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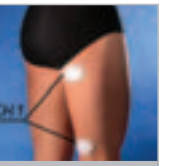

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